



November 2008



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For all the latest information, visit [www.usp.org](http://www.usp.org)

## Reference Standards Highlights

Below are several tables with the latest Reference Standard information including out-of-stock items now available; new Reference Standards released in October 2008; backordered items with estimated availability dates; items that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.

Please contact your USP Customer Service Representative to place an order at +1 (301) 881-0666 or 1-800-227-8772. European customers can call 00-800-4875-5555. You can also order online at [www.usp.org/products](http://www.usp.org/products).

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**New Reference Standards Now Available**

Catalog #	Description	Size	Lot	Price (USD)
1046045	Azithromycin Related Compound F	25 mg	F0H313	\$576
1096633	Carvedilol Related Compound A	15 mg	F0H146	\$576
1096644	Carvedilol Related Compound B	15 mg	F0H192	\$576
1096677	Carvedilol Related Compound E	15 mg	F0H201	\$576
1134120	Cisapride	200 mg	F0H112	\$185
1151935	Cyanidin-3-O-Glucoside Chloride	15 mg	F0H218	\$500
1162432	Daidzin	30 mg	F0H251	\$616
1234307	Eicosapentanoic Acid Ethyl Ester	500 mg	F0H170	\$500
1265537	Ethylhexyl Triazone	200 mg	F0H178	\$185
1270424	Fish Oil	1 g	F0G015	\$185
1286118	Formoterol Fumarate System Suitability Mixture	20 mg	F0H166	\$673
1288816	Genistein	15 mg	F0H252	\$185
1295844	Glycitein	15 mg	F0H234	\$639
1295855	Glycitin	15 mg	F0H235	\$489
1354251	Itraconazole	100 mg	F0H188	\$185
1356563	Ketoprofen Related Compound D	20 mg	F0H249	\$576
1356778	Lamotrigine Related Compound B	20 mg	F0H261	\$576
1356789	Lamotrigine Related Compound C	10 mg	F0H280	\$576
1356790	Lamotrigine Related Compound D	10 mg	F0H279	\$576
1362114	Levofloxacin Related Compound A	25 mg	F0H189	\$576
1362125	Levofloxacin Related Compound B	35 mg	F0H190	\$576
1444296	Mirtazapine Resolution Mixture	25 mg	F0H233	\$738
1491365	Paclitaxel Impurity Mixture	10 mg	F0G368	\$576
1494931	Pantoprazole Related Compound D and F Mixture	20 mg	F0H260	\$576
1494942	Pantoprazole Related Compound E	20 mg	F0H271	\$576
1612619	N-Acetylneuraminic Acid	200 mg	F0H186	\$185
1672701	Trandolapril Related Compound C	25 mg	F0H176	\$576

**Previously Out-of-Stock Items Now Available**

Catalog #	Description	Size	Lot	Price (USD)
1012065	Acyclovir	300 mg	J1G366	\$233
1045009	Atropine Sulfate	500 mg	N0H159	\$185
1071009	Bethanechol Chloride	200 mg	I0H206	\$185
1146006	Colchicine	350 mg	L0H214	\$185
1223005	2,4-Disulfamyl-5-Trifluoromethylaniline	30 mg	H0H040	\$576
1374500	Maleic Acid	300 mg	H0H121	\$576
1441301	Metoprolol Tartrate	200 mg	I0G301	\$185
1499414	Paricalcitol Solution	3 mL	G0H292	\$295
1524001	Phenobarbital CIV	200 mg	K0H134	\$245
1547007	Polymyxin B Sulfate	200 mg	L0H010	\$185
1601623	Residual Solvent Class 2 – Methanol	3 x 1.2 mL	G0H294	\$185
1613804	Sodium Chloride (AS)	1 g	G0H275	\$185

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**Backorder Availability Estimates, October 27, 2008**

Catalog #	Description	Expected Availability*
1032007	Amphotericin B (125 mg)	Q4/08
1044800	Atracurium Besylate (100 mg)	Q4/08
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q4/08
1068004	Betamethasone Sodium Phosphate (500 mg)	Q4/08
1410002	Methicillin Sodium (500 mg) (AS)	Q4/08
1471007	Norethynodrel (200 mg)	Q4/08
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	Q4/08
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08

\*Dates are targets and may change at any time. Q4/08=October–December 2008

**Items with New Package Size**

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1146006	Colchicine	300 mg	350 mg	LOH214	\$185

**RS Lots That are No Longer Valid**

This Table lists previous RS lots that are (or will soon be) no longer valid for official use. If you still have any of these materials on hand, do not use them for compendial testing purposes after the last day of the month for the valid use dates listed. To test products, always be sure you use a current, valid lot of USP RS. Current lot numbers and valid use dates for previous lots are available in the USP Catalog online at [www.usp.org](http://www.usp.org): click on the USP Products link and look up the RS of interest.

No Longer Valid as of October 31, 2008					
Catalog #	Description	Previous Lot/ Valid Use Date		Current Lot	Price (USD)
1027302	Amiodarone Hydrochloride (200 mg)	F0D257	(10/08)	G0G340	\$185
1145003	Codeine Sulfate <b>CII</b> (250 mg)	H-2	(10/08)	I0G213	\$245
1154569	Beta Cyclodextrin (250 mg)	G	(10/08)	G1G216	\$185
1170000	Demeclocycline Hydrochloride (200 mg)	H1C036	(10/08)	H2G314	\$185
1268604	Etidronic Acid Monohydrate (1 g)	G	(10/08)	G1G218	\$185
1285807	Flurbiprofen Sodium (200 mg)	F	(10/08)	G0G056	\$185
1305008	Hexachlorophene (500 mg)	I	(10/08)	J0G217	\$185
1327000	Hydroxychloroquine Sulfate (200 mg)	J0B297	(10/08)	K0G211	\$185
1341001	Indomethacin (200 mg)	J0B165	(10/08)	J1G345	\$185
1375058	Mandelic Acid (500 mg) (AS)	F	(10/08)	G0H130	\$185
1392002	Mercaptopurine (500 mg)	I2C263	(10/08)	J0G300	\$185
1485191	Oxycodone <b>CII</b> (200 mg)	J0F026	(10/08)	K0G276	\$245
1586009	Pyridostigmine Bromide (200 mg)	I0C324	(10/08)	J0G251	\$185
1674004	Tretinoin (30 mg/vial; 5 vials)	J0D145	(10/08)	J1F266	\$185
1708795	Valsartan Related Compound C (10 mg)	G0F241	(10/08)	G2H042	\$738



No Longer Valid as of November 30, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1019701	Amiloride Hydrochloride (500 mg)	H (11/08)	H1G197	\$194
1056504	1,4-Benzoquinone (200 mg)	G1B145 (11/08)	H1G332	\$194
1078700	Buprenorphine Hydrochloride <b>CIII</b> (50 mg)	G0E026 (11/08)	H0G362	\$257
1078711	Buprenorphine Related Compound A <b>CII</b> (25 mg)	F1C076 (11/08)	G0G353	\$605
1083100	3-tert-Butyl-4-hydroxyanisole (200 mg)	L0E259 (11/08)	M0G066	\$194
1130527	Chlorzoxazone Related Compound A (50 mg)	G-1 (11/08)	H0G336	\$605
1134029	Ciclopirox Related Compound A (25 mg)	F0E087 (11/08)	G0G212	\$605
1477003	Nystatin (200 mg)	O0D177 (11/08)	O1G308	\$194
1491332	Paclitaxel (200 mg)	G0E018 (11/08)	H0G193	\$1,874
1494079	Pancreatin Lipase (2 g)	I1E327 (11/08)	J0G363	\$194
1530503	L-Phenylalanine (200 mg)	H (11/08)	I0G255	\$194
1570304	Propafenone Hydrochloride (200 mg)	G1C184 (11/08)	H0F302	\$194
1625009	Sulfadiazine (200 mg)	J (11/08)	J1G290	\$194

Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012065	Acyclovir (300 mg)	J0C149 (10/09)	J1G366	\$245
1071009	Bethanechol Chloride (200 mg)	H0E304 (10/09)	I0H206	\$194
1146006	Colchicine (350 mg)	K0F231 (09/09)	L0H214	\$194
1268728	Etodolac Related Compound A (25 mg)	F-1 (10/09)	F2G334	\$605
1292314	Glimepiride Related Compound A (20 mg)	F0E232 (10/09)	F1H269	\$605
1370349	Lorazepam Related Compound C (25 mg)	H (10/09)	I0H232	\$605
1374500	Maleic Acid (300 mg)	G (10/09)	H0H121	\$605
1541500	Piperacillin (500 mg)	H (10/09)	I0H009	\$194
1601623	Residual Solvent Class 2 - Methanol (1.2 mL/ampule; 3 ampules)	F0D045 (07/09)	G0H294	\$194

USP Residual Solvents Reference Standards for <467> Compliance

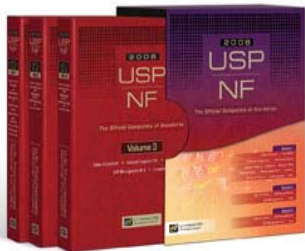

USP encourages all global manufacturers of drug substances, excipients, and drug products to conform to the standards delineated in the *USP–NF* General Notices and General Chapter <467> Residual Solvents (official July 1, 2008). To assist manufacturers, USP has developed 36 new residual solvents Reference Standards designed to support <467> procedures. These standards were manufactured in a GMP facility and contain the class 1 or class 2 solvent mixed in pure DMSO. View list of and purchase current USP residual solvents Reference Standards [here](#).

Visit the Residual Solvents Hot Topics page with <467> resources at [www.usp.org/hottopics/residualsolvents.html](http://www.usp.org/hottopics/residualsolvents.html).

[Register now](#) for a one-day lecture focusing on Chapter <467> implementation, misconceptions, and developing alternative validation methods.



## USP Publication Highlights

	<p><b>Be Prepared for 2009—USP 32–NF 27 is Available Now!</b></p> <p>The new <i>USP–NF</i> just published. Available now in English (print, online, and CD formats), an annual subscription includes a main edition and two <i>Supplements</i>. The <i>USP 32–NF 27 Spanish Edition</i> (print only) publishes in January 2009. Subscribe today at <a href="http://www.usp.org/products/USPNF">www.usp.org/products/USPNF</a> or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).</p>
	<p><b>Pharmacopeial Forum (PF)—Product Redesign Announcement</b></p> <p>Effective January 1, 2010, <i>PF</i> will be launched as a complimentary online service to the public. At that time, <i>PF</i> will no longer be offered in print format and all print and online paid subscriptions will expire. To learn more about the upcoming <i>PF</i> product changes, please visit <a href="http://www.usp.org/USPNF/pf/pfRedesign.html">www.usp.org/USPNF/pf/pfRedesign.html</a></p>

### Publications Scheduled Ship Dates

The following table lists the scheduled ship dates for USP publications.

Publication	Scheduled Ship/Post Date
USP32–NF27 Print	Already Shipped
USP32–NF27 Online	November 3, 2008
USP32–NF27 CD	November 3, 2008
PF 34(6) Print	November 7, 2008

Orders should arrive within two weeks of placement. If you do not receive your publication order when expected, please contact USP Customer Service at +1-301-881-0666 or email [custsvc@usp.org](mailto:custsvc@usp.org)

## Event Highlights

### USP Customer Days—Coming to a City Near You!

The USP Account Management Team will be traveling across the U.S. and Canada holding free seminars to discuss USP publications, Reference Standards, USP Verified Services, Professional Education, new initiatives, and scientific hot topics. **Meetings are scheduled for Columbus, OH (December 2, 2008);** Northern CA (February 2009); Toronto, Canada (March 2009); and Rockville, MD (May 11, 2009). Registration and more information are available at <http://www.usp.org/products/USPCustomerDays/> or contact: [uspcustomerday@usp.org](mailto:uspcustomerday@usp.org).



## Pharmacopeial Education

### Featured Courses

#### **Residual Solvents: Practical Applications <467>**

Hosted by GERSTEL, Inc., USP Senior Scientist Dr. Horacio Pappa presents this custom one-day lecture focusing on implementation, misconceptions, and developing alternative validation methods. Course is being conveniently held next to the BWI airport.

- Review guidelines contained in Chapter <467>
- Discuss common mistakes and misconceptions in the implementation of the new standards
- Illustrate Option 1 and 2, as well as procedures A, B, and C
- Introduce risk-based strategy concept when dealing with compliance issues
- Explain how to develop and validate alternative methods
- Q&A session with Dr. Horacio Pappa to address your specific concerns

**Classroom Cost:** US \$695

**Date and Location:** December 11, 2008; Linthicum, MD; [click here](#) to register.

#### **USP/ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety**

USP and ISMP bring you this one-day interactive course designed for pharmacy directors/managers, risk managers, patient safety officers, medication safety officers, and other healthcare professionals seeking to enhance their ability to collect, analyze, and prioritize adverse drug event data.

- Identifying risk points and the correlated benefits and limitations of various methods of collecting data
- Transforming aggregate data into meaningful information
- Calculating the costs of error events
- Presenting data to frontline staff and management
- Distinguishing between high- and low-leverage error reduction strategies

**Classroom Cost:** US \$350-\$450

**Date and Location:** December 6, 2008; Orlando, FL; [click here](#) to register.

#### **Free On-Demand Courses!**

On-demand courses available now for free. (Click course title for more information, or click "View" to take the course.)

[Introduction to the New FCC](#)

[View](#)

[Navigating the FCC](#)

[View](#)

[How to Use the FCC Forum—Making the FCC Your Own](#)

[View](#)

[How to Develop an FCC Monograph](#)

[View](#)



## Compounding Sterile Preparations—<797> Webinar Series (\$150 per course)

On-demand courses available at a fraction of the cost for a live classroom experience.

<a href="#">Microbial Contamination and Sterilization</a> (\$150)	<a href="#">“Register”</a>
<a href="#">Disinfectant Cleansing and Garbing</a> (\$150)	<a href="#">“Register”</a>
<a href="#">Microbial Contamination, Media Fill Testing, and Hazardous Drugs</a> (\$150)	<a href="#">“Register”</a>
<a href="#">Environmental Monitoring Controls and Facility Design</a> (\$150)	<a href="#">“Register”</a>
<a href="#">Radiopharmaceuticals, Sterilization Methods, and Specialty CSPs</a> (\$150)	<a href="#">“Register”</a>

## Upcoming PE Courses Worldwide

- [USP/ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety](#)
- [Dissolution: Theory and Best Practices](#)
- [Advanced Dissolution](#)
- [Validation of Compendial Procedures](#)
- [Essentials of Microbiological Testing](#)
- [Effectively Using USP–NF](#)
- [Aseptic Processing and Compliance Tools for USP <797>](#)

## Subscribe to the Pharmacopeial Education Email Bulletin

USP Pharmacopeial Education is developing several new courses for introduction in 2008 and 2009. If you would like to stay informed of our new curriculum and upcoming schedule, [subscribe now](#) to the Pharmacopeial Education Bulletin.

For the complete USP Education course list, please go to

<http://www.usp.org/education/pe/courses.html>



## Compendial Highlights

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### [USP–NF Notices](#)

Sign up to receive Notices electronically at

<http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial>

**Revision Bulletins:** [Protamine Sulfate Monograph](#) (10/24/08)

**Explanatory Notes/Announcements:** Nothing New

**Intent to Revise:** Nothing New

**Errata:** Nothing New


**Postponements:** Nothing New

**General:** Nothing New

### [Stimuli Articles](#)

Featured in *PF 34(6)*, November–December 2008

[USP Responses to Comments on Stimuli Article: The Application of Uncertainty to USP's Compendial Reference Standards Program: Certified Reference Materials](#)  (527KB)

[The Use of Inductively Coupled Plasma–Optical Emission Spectroscopy in the Determination of Heavy Metals in Crospovidone and Povidone as a Replacement for the Concomitant Visual Comparison Test](#)  (527KB)

[Compendial Calculations: Recommendations for Improving USP–NF Calculations](#)  (527KB)

[General Chapter Containers–Packaging Auxiliary Components <670>](#)  (527KB)

[Description of the Upcoming Change in Data Analysis for USP Dissolution Performance Verification Tests](#)  (527KB)

[USP Responses to Comments on Stimuli Article Uncertainty Statements Regarding USP Reference Standards](#)  (527KB)

[Redesign of the United States Pharmacopeia and National Formulary](#)  (527KB)

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## Tip of the Month

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**Monograph Redesign**—USP is seeking comments for proposed design changes to all monographs contained in the *USP–NF*. Beginning, November 3, redesigned monographs are being posted on a staggered basis in alphabetically ordered sets on <http://www.usp.org/monoRedesign/> for comment for 90 days. This is your chance to become familiar with the new formats and identify any errors that may have been introduced through the conversion of the monographs to this new style. The new format will be incorporated in *USP 33–NF 28*. Click [here](#) for more details.

## Question of the Month

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***What does USP on the label of an article indicate?***

The use of "USP" means that there is an applicable USP monograph for that article, and that the article "purports to comply with all applicable USP standards." See General Notices, USP 31, second paragraph under heading "'Official' And 'Official Articles'". The use of "USP" does not imply more (e.g., whether the article complies with other applicable standards, or was manufactured in conformance with GMPs).

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